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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,013	08/05/1999	DEBORAH KNUTZON	CGAB-210-USA	3773

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SAN FRANCISCO, CA 94111-4067

EXAMINER

NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/06/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/367,013

Applicant(s)
Knutzon et al.

Examiner
Nashaat T. Nashed

Art Unit
1652



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 7, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 189-244, 255-290, and 297 is/are pending in the application.
- 4a) Of the above, claim(s) 189-214 and 285-290 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 215-224 and 255-264 is/are allowed.
- 6) ☒ Claim(s) 225-244, 265-284, and 297 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

The application has been amended as requested in the communication filed July 7, 2003. Accordingly, claims 291-296 have been canceled, claims 189, 193, 201, 205, 208, 214, 215, 225, 235, 255, 265, and 275, and new claim 297 has been entered.

Claims 189-214 and 285-290 remain withdrawn from further consideration. As indicated in the previous Office action, the claims in this application has been previously restricted in paper number 12, and applicants made an election without traverse of both the elected method and the species. Nevertheless, Applicants traversed the restriction in the previous response, their traversal was considered, and the restriction requirement was made **Final** in paper number 24.

This application contains claims 189-214 and 285-290 are drawn to an invention nonelected with traverse in Paper No. 23. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 215-244, and 255-284 and 297 are under consideration.

The amendment filed July 7, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "nucleic acid hybridizes preferentially to the complement of the sequence depicted in SEQ ID NO: 1 at 50 degree Celsius in 60 mM Tris-C; (pH8.5) and 15 mM ammonium sulfate and 2 mM magnesium chloride" in new claim 297.

Applicant is required to cancel the new matter in the reply to this Office Action.

New claim 297 is objected to because of the following informalities: "Tris-Cl" should be "Tris-HCl". Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 225-244, 265-284, and 297 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to methods of a lipid fraction enriched in stearidonic acid using yeast transformed with the nucleic acid sequences encoding Δ -6-

desaturase of SEQ ID NO: 2 including SEQ ID NO: 1 from *Mortierella alpina* for the reasons set forth in the prior Office actions, see papers numbers 15, 20, and 24.

Applicants argue that it is erroneous to make an enablement rejection based on analysis of only one of the Wands' factors, and discussed each of the Wands' factors from their point of view.

Applicants' arguments filed 7/7/03 have been fully considered but they are not deemed to be persuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. The previous Office actions sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning why a person of ordinary skill in the art would doubt that the guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants merely assert that the disclosure of the nucleic acid sequences and the teaching of the specification is sufficient enablement for the claims. The examiner disagrees with applicants views of the rejections made in the previous Office actions. Applicants are advised to review the first Office action on the merit which has a detailed discussion of the Wands' factors as they relate to the claims of the instant application. The narrowing of the scope of the claims from 50% or 60% has not changed the issues very much because the claims reading on a method using nucleic or amino acid sequence having 80% sequence homology to SEQ ID NO's: 1 or 2, respectively. While the specification teach general mutation methods, it does not teach any methods which would enable one of ordinary skill in the art to redesign 20% of the nucleic sequence of SEQ ID NO: 1 or the amino sequence of SEQ ID NO: 2 and maintain the ability of the polypeptide to fold and have the desaturase activity between C-6 and C-7 without undue experimentation. Applicants are surely aware that such methods are not known in the prior art or even today. Similar to claim 275, claim 297 is directed to a method utilizing nucleic acid sequence that hybridizes to SEQ ID NO: 1 under any hybridization conditions. The new matter in claim 297 should be deleted. Applicant should note that the new matter in claim 297 cites conditions for PCR experiment, see example 3 on page 49, lines 10-21, which tends to enhance the hybridization of a probe to a potential gene through high ionic strength (15 mM ammonium sulphate) at a relatively low temperature (50 degree Celsius). There is no such a hybridization condition known in the prior art and, if it exists, it would be a very low hybridization conditions.

Claims 275 and 297 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) The phrases "hybridizes preferentially to the complement of the sequence depicted in SEQ ID NO: 1" under hybridization conditions suitable for sequencing said complement" in claim 275 renders the claim indefinite and confusing, respectively, because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Since nucleic acid are known to hybridize to any other nucleic acid sequence under different conditions, the nucleic acid sequence of SEQ ID NO: 1 is expected to hybridize to any nucleic acid sequence. Thus, the claim is considered indefinite. Since the specification does not contain any specific hybridization conditions, the claim can't be amended to obviate this rejection. The new phrase "under hybridization conditions suitable for sequencing said complement" is not defined or found in the specification and one of ordinary skill in the art would not know its meaning. The phrase constitute a new matter and should be deleted.
- (b) Claims 276-284 are included in this rejection and do not cure the deficiencies of the claims from which they depend.

Applicants has not responded to the above rejection and reference the last response. Since applicants' response to the previous Office action was considered fully and responded to in paper number 24, and no new arguments have been forward with the instant response, the rejection remains proper.

- (c) The phrase "nucleic acid hybridizes preferentially to the complement of the sequence depicted in SEQ ID NO: 1 at 50 degree Celsius in 60 mM Tris-C; (pH8.5) and 15 mM ammonium sulfate and 2 mM magnesium chloride" in new claim 297 renders the claim indefinite and confusing, respectively, because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The specification describe the above condition for PCR experiment and not for hybridization condition, and thus, the phrase is considered new matter. For examination purposes only, the conditions is eliminated from the claim.

Claims 215-224 and 255-264 are allowed.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Serial Number: 09/367,013

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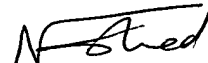
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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Nashaat T. Nashed, Ph. D.
Primary Examiner